

DIVISION OF HEALTH PROFESSIONS LICENSURE
STRATEGIC PLANNING INTERIM REPORT

FEBRUARY 2014

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EXECUTIVE SUMMARY

In 2011, the Bureau of Health Care Safety & Quality (BHCSQ) began a series of strategic planning efforts that have so far culminated in the transformation of the Office of Emergency Medical Services, the re-structuring of the Drug Control Program, and innovations in the Center for Patient Safety. These efforts are part of the Bureau's commitment to re-positioning its resources to better support patient safety and the quality assurance requirements of a rapidly changing health care environment.

Preliminary administrative and programmatic review was underway in the Division of Health Professions Licensure (HPL) in the fall of 2012 when the compounding pharmacy emergency began unfolding. For six months, the management and resolution of the initial phases of the compounding problems demanded the full focus of the Division. In February 2013, strategic planning for all of HPL began again in earnest with the recommendations of the Special Commission on the Oversight of Compounding Pharmacies (Special Commission) and the Governor's proposed legislation providing a backdrop for a cross-boards assessment of the Division's current administrative and enforcement activities.

This interim report provides a point-in-time summary of the progress so far. Substantial operational and other health care safety and quality related analyses have been completed, providing the baseline for recommended actions over the course of the next year. In some cases, administrative and procedural changes have already been put in place; others await further internal and external deliberation, including with the respective HPL Boards; and some rely on decisions that will need to be forthcoming regarding resource allocation, personnel and contractual functions, and the implications of adopting a Just Culture stance as recommended by the Special Commission.

The strategic planning process has as its primary goal the improvement of health care quality and safety in those practice arenas regulated by the HPL Division. Three pragmatic objectives have shaped the work so far:

- Maximize the extent to which the Division's activities reflect national best practices;
- Align cross-Board policies and administrative functions wherever possible; and
- Identify opportunities for improved efficiency.

While a large part of the work appropriately focused on the Pharmacy Board and the particular concerns regarding compounding pharmacies, the Division and the Bureau recognized the joint interest and benefit to all HPL Boards of building a better and, wherever possible, shared platform for the future of quality improvement in the health professions.

The planning has taken place in a context of still evolving national debate regarding the role of health professions boards. Some of the debate is situated in the requirements of a changing health care delivery and financing environment; some is a reflection of shifting perspectives regarding public interest, industry self-regulation, and the roles of government

licensing boards; and some is located in the struggle to address medical error and responsibility in the context of a Just Culture that is committed to strong enforcement.

With ongoing change as a backdrop, this report attempts to situate findings and recommendations as much as possible in current best practices and recognizes that quality improvement will occur as the arena of Health Professions Licensure continues to develop, as administrative authority and needed infrastructure become available, and as the calculus of flexibility and discretion in risk management and enforcement evolves.

This interim report includes recommendations in three major categories that address HPL functions across Boards:

- Improved Risk Management and Enforcement;
- Improved Quality and Efficiency; and
- Improved Transparency and Customer Service.

Most of the recommendations address organizational change issues, including workflow and Board member and staff roles and functions; many require regulatory or policy development; and some will rely upon new or re-aligned analytic, IT, and other resource allocation. An addendum to the report includes a comprehensive summary of compounding pharmacy related work that occurred during this period. The table below provides a high level summary of the Interim Strategic Plan elements.

The strategic planning process builds on the considerable contributions of HPL Board members and staff over time and their continuing efforts to assure the safety and quality of care in the Commonwealth.

Interim Strategic Plan Components

Risk Management & Enforcement	<ul style="list-style-type: none">•Acuity-based Complaint Management•Standardized Complaint & Discipline Policies & Procedures•Increased Industry Self-management & Report•Secure Board Communications Platform•Just Culture Framework•Improved Investigational Guidance & Analytics
Quality Improvement & Efficiencies	<ul style="list-style-type: none">•Continuous Quality Improvement Plan•Comprehensive Board & Staff Capacity Development•Expanded Board Delegation / Staff Authority•Common Licensing Platform / Management•Centralized CORI, CEU, & other Licensee Quality Assurance
Transparency & Customer Service	<ul style="list-style-type: none">•Expanded Web-based Complaint Disposition and other Board Membership & Meeting Information•New Division Annual Report•Improved Stakeholder Engagement•Improved Web-based and other Customer Service

I. BACKGROUND ON THE HEALTH PROFESSIONS LICENSURE DIVISION

The Division of Health Professions Licensure (HPL) has been a unit within the Department of Public Health (DPH) since January of 2003 when seven health care boards of registration were transferred from the Office of Consumer Affairs and Business Regulations, Division of Professional Licensure (OCA/DPL). Currently, HPL is a Division within the Bureau of Health Care Safety and Quality and consists of nine boards of registration (Nursing, Pharmacy, Dentistry, Physician Assistants, Respiratory Care, Nursing Home Administrators, Perfusionists, Genetic Counselors, and Community Health Workers). The primary mission of these boards is to protect the health, safety and welfare of the public by licensing qualified health care professionals, services and facilities through the fair and consistent application of statutes. In open forums, the HPL Boards of registration develop, implement and enforce regulations and policies that assure and promote safe practice of the professionals and businesses under their oversight. As of July 1, 2013, HPL licensed, registered, certified or authorized approximately 196,354 health care professionals and businesses. HPL's staffing level included 74.8 full-time equivalent active staff. HPL and its nine health boards of registration are funded by a combination of three state appropriations and the Quality in Health Professions Trust Fund. The total combined available funding in FY13 was \$9,322,265.

The Division seeks to support ongoing quality improvement in the various disciplines through a variety of informational and stakeholder communications. HPL Boards investigate complaints and take disciplinary action against licensees whose conduct harm or creates risk of harm to the public by engaging in unethical, incompetent or improper conduct. Last year, Division Boards resolved 717 formal complaints against health professionals or facilities; 296 or 41% of these complaints were resolved with disciplinary action.

HPL also administers the Massachusetts Professional Recovery System (MPRS) for licensed health professionals (dentists, pharmacists, respiratory therapists, and allied health professionals). MPRS is a five-year monitoring program that assists licensed health professionals with alcohol and/or other drug problems in their efforts to return to practice safely. In addition, the Board of Registration in Nursing administers the Substance Abuse Rehabilitation Program (SARP) that is established by M.G.L. c. 112, § 80F as a voluntary, non-disciplinary approach to substance abuse among licensed nurses. SARP is a five-year abstinence-based program to assist nurses whose competency has been impaired by the use of, or dependence on, alcohol and/or other drugs to return to nursing practice. SARP is designed to protect the public health, safety and welfare by establishing adequate safeguards to maintain professional standards of nursing practice while monitoring and supporting participants' ongoing recovery and their return to safe nursing practice.

The following sections II-IV, detail the interim plan developments in each of the three strategic areas of program and administrative improvement.

II. IMPROVING RISK MANAGEMENT AND ENFORCEMENT

A. Risk Management strategies focused on opportunities to improve internal complaint management and related operations, practitioner and facility review, and Board functioning. For each strategy the status of its implementation and/or ongoing need for development is noted.

- **Case Stratification and Acuity-based Management:** HPL has developed a new system of case stratification intended to assure immediate internal notification to the Division Director, and beyond as appropriate, regarding those complaints that pose differential risk to the public. The stratification of cases by acuity is also intended to drive investigational and case management processes appropriate to the risk of the complaint and eventually to inform an internal dashboard that will allow for more expeditious review of the status of cases by the Division and Bureau Directors. Standardized reports reflecting the status of investigations will be available through the Division's licensing and complaint software system, MLO (My License Office), and the data can be incorporated into the HPL Division-wide critical incident management policy that will be finalized in the spring. Additional critical incident data reporting across all Boards is under review. Finally, a series of guidelines and evidence management policies have been newly drafted to assure standardization in case investigation and chain of custody evidence management.
- **Status:** Case stratification began in May; a formative review of its application across the Boards was conducted during July 2013; analysis of the sample is underway and written policy and procedures are under development. Piloting of the system began in the fall of 2013 and is ongoing

New and updated preliminary complaint investigation and disposition management policies, procedures and guidelines were drafted including, among others, Complaint Investigation Priorities and Process Timelines, Guidelines for Standard Investigation Activities, Guidelines for Handling Evidence and Chain of Custody Log, Complaint Intake and Triage Process, General and Board Specific Operational and Administrative Procedures, Investigation Guidelines, Record Storage and Retention Procedures, Information Release and Public Record Request Policies and Processes, and Probation Monitoring Activity Procedures documents.

A Sterile Compounding Pharmacy Inspection Log was established in the spring of 2013. Weekly critical incident reports and a triage process have been put in place and a Product Recall Checklist has been drafted and is under review. New policies for managing communication about Abnormal Results, Pharmacy Retail Drug Store Closures, and procedures for handling incoming reports of Theft or Loss of Controlled Substances from DEA will be completed this spring. These efforts will inform both an updated reporting process for compounding pharmacies as well as development of the new division-wide critical incident management policy.

- **Practitioner and Facility Risk Assessment, Mitigation & Communication:** HPL is committed to assuring the adoption of best practices in the identification, mitigation and, as appropriate to those goals, public communication of practitioner and facility safety and quality concerns. To that end, HPL has conducted a multi-state and across-HPL Board review of current policy approaches to: Criminal Offender Record Information review (CORI), Good Moral Character (GMC), cross-state reciprocal discipline practices, and probation monitoring in health professions boards, among others. Additionally, HPL initiated an assessment of the status of discipline-based self-audit / management efforts; identified and reviewed numerous state compounding pharmacy regulations; and reviewed state practices in website and other public notification of practitioner and facility complaints.

- **Status:** As a first step to improved and consistent CORI related management, the HPL Division has decided to centralize CORI processing across the Boards. Policies and procedures regarding CORI management practices, good moral character determination (GMC), reciprocal discipline, probation monitoring, and other provider risk management practices are nearing final completion. Currently, HPL is exploring the permissibility of performing data matching with the Sex Offender Registry Board.

Expanding the requirements of disciplines to conduct self-audits and expanding industry-based self-management responsibilities is an increasing aspect of health professions licensing, quality assurance and safety strategies nationally. A review of HPL Board self-audit and other industry self-management strategies was conducted and a model effort in California was extensively reviewed. Further active engagement of facilities in self-audit practices is planned through upcoming web-posting and technical support regarding practitioners' use of the Dental Board's site inspection tool; the Board of Pharmacy's planned compounding pharmacy inspection tool and an anticipated self-assessment for sterile compounding pharmacies.

By emergency regulation in December 2012, compounding pharmacies were required to submit sterile compounding semi-annual summative data reports on the range of their compounded products, their volume and distribution parameters. The third filing was received in January of this year and a report from all sterile compounding pharmacies will be due on a semi-annual basis on the 15th of every January and June. Future reports and summary analyses will conform to new statutory requirements. An access database has been developed to capture all report responses going forward; results will be posted on the Board of Pharmacy website.

Best practices in compounding pharmacy regulations nationally were identified and compiled as a source document to inform Massachusetts regulatory and other policy development prioritized by the Division. Additional research was conducted in areas for which best practices are still evolving, including product recall, pharmacy retail drug store closures, and cross-state notification. HPL staff review and identification of regulatory and administrative pharmacy practice options will be completed in 2014. A New England Compounding Pharmacy Consortium was also established last fall to facilitate timely inter-state information exchange.

- A multi-state review of health professions websites reporting board complaint reviews, sanctioning, quality and safety alerts was completed with a focus on current practices in VA, FL, MN, MD, WA. Options for improving Massachusetts related web-based data on Board actions and safety information are currently under review. A draft template for a standardized approach within HPL will be completed by summer 2014. All Board meeting minutes and agendas, for the Board of Registration in Pharmacy, have been posted from 2011-2013.

Current IT management processes pose challenges in terms of timely posting and web content management; additionally, building a best practice website capacity and addressing the requirements of the Special Commission and the recent legislation may require further and more direct access to IT systems management.

HPL has engaged EOHHS and Bureau IT in a meeting regarding website development and plans to work cooperatively to achieve its IT needs.

Finally, standardized communications regarding complaints are under development and will be a part of a template library embedded in the MLO system to assure consistent notification regarding complaints, incidents, and licensee reporting requirements. This library is expected to be developed and completely embedded into the MLO system by the end of 2014.

- **Board composition, transition, and communications:** Nationally the structure of health professions boards has been under review for over a decade with a particular emphasis on diversifying discipline-based and public membership as well as minimizing conflict of interest. Some of these concerns were the backdrop for recommendations from the Special Commission for the Pharmacy Board and are reflected in the recent legislation. As with other core strategic planning areas, HPL initiated a cross-Board and national review of best practices to assess not only Board composition and conflict of interest issues but also to determine optimal and alternative strategies for managing Board members' term appointments and transitions, especially in the face of sub-quorum capacity that has impacted some HPL Board processes. Finally, staff assessed strategies for improving communication support and document management for Board members.
 - **Status:** Regarding improved communication support for Boards, HPL recently implemented a secure communications platform for all Boards. Once initial technical issues have been resolved, this should greatly improve timely reporting to Board members of high risk circumstances as well as facilitate easier document review for Board action. In order to assure systematic approaches to Board public communications and case file management, HPL is instituting standardized public meeting and other Board reporting formats and a centralized process for closed case document management which was recently put in place within the Division.

In the arena of Board composition and transition, HPL completed a review of all vacancies and sitting members' term status. As of July 30, 2013, most new and reappointment recommendations have been forwarded to the Commissioner for expedited management; the Division anticipates fully seated Boards during the current year.

Addressing conflict of interest, succession and Board vacancy concerns is an ongoing issue nationally in terms of risk management and quality assurance for public health professions boards. A multi-state assessment of professional licensing boards' composition and management practices included reviews of various health professions licensure boards in California, Minnesota, Virginia and New York. A review of all HPL Boards relative to these parameters is underway. Senior HPL staff discussion is planned for this spring; Board discussions will occur in the fall, pending review of internal recommendations.

B. Enforcement strategy work focused on: building a structured approach to adopting and implementing a Just Culture¹ philosophy across Boards and staff; identifying opportunities

¹ ...a just culture recognizes that individual practitioners should not be held accountable for

to improve and standardize Board complaint resolution and disciplinary practices across diverse complaint categories; and undertaking strategic workforce development, including increasing staff, expanding training, and re-organizing personnel functions to improve enforcement practices, including post-disposition probation monitoring.

- **Just Culture development:** In line with other medical error investigation, complaint resolution, and enforcement developments, the Special Commission recommended that the Board of Pharmacy and all of DPH – adopt Just Culture as the framework for assuring patient safety and care quality. HPL is moving forward with incorporating a Just Culture approach into its investigational and enforcement activities.
 - **Status:** HPL will conduct an all-Board and senior staff training on Just Culture in 2014. In preparation for the training, an assessment of the implications of a Just Culture approach across investigational and complaint resolution functions are now underway. Recommendations forthcoming from the current best practice reviews of practitioner risk management and discipline will be examined in light of meeting Just Culture objectives and will be a point of reference for these trainings. Among the resources under review to support these trainings are products from the Just Culture Community (<https://www.justculture.org/>), an active review of alternative change management strategy approaches, and Just Culture presentations at the October *Council on Licensure Enforcement and Regulations (CLEAR)* conference.
- **Improving and standardizing Board complaint management, disposition and disciplinary practices:** Preliminary internal reviews of a cross-Board complaint management system resulted in the identification of some differential approaches to similar cases. HPL intends to standardize complaint management and disposition, across all Boards in the absence of evidence-based rationale for different treatment.
 - **Status:** As noted in the previous section, national best practice reviews and proposed policy and regulatory options have been developed regarding complaint resolution activities in anticipation of adopting, to the maximum extent possible, consistent complaint management and disposition practices across the Boards. Division senior management has reviewed these and any changes that go beyond the Division's administrative authority will begin to be presented to the Boards for deliberation in 2014.

Additionally, a full review of Division fining authority and strategies for increasing collection is underway and has included a review of existing peer reviewed literature in this arena. Findings and recommendations will be reviewed by the Bureau Director in anticipation of Commissioner Office review

system failings over which they have no control. A just culture also recognizes many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts "no blame" as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated). Excerpted from: Marx D. Patient Safety and the "Just Culture": A Primer for Health Care Executives. New York, NY: Columbia University; 2001. Available at: <http://www.safer.healthcare.ucla.edu/safer/archive/ahrq/FinalPrimerDoc.pdf>

in 2014. Additional collection authority may need to be requested in the FY2015 budget process.

- **Division reorganization, workforce development, and improved investigational guidance and analytics:** A cross-board assessment of investigation practices, personnel, and workflow was undertaken with the goal of determining needed competencies, opportunities for redundancy, and consistent investigational and other complaint management.
 - **Status:** Investigation staff has been trained on the new case stratification and management process and corresponding written policies and procedures are currently being completed. The recent hiring of a Chief Board Counsel, a new position, will bring systematic oversight, content expertise, and consistency to enforcement activities across the boards. The Chief Board Counsel is also a member of the HPL senior management team. Additionally, HPL plans to hire an additional staff member to help build the analytic infrastructure and reports needed to assess the status and progress of investigational and enforcement activities on an ongoing basis.

Assuring consistent practices among investigators is crucial to supporting effective enforcement. A Division-wide Investigation Report policy and procedure is under review and will be implemented in 2014. Similarly, the Strategic Plan process revealed the absence of written policies and procedures for Administrative Hearing Officers; those are also under development and are expected to be in place before the end of 2014.

A planned comprehensive training strategy which will include, among other components, expanded interview training for investigators and interpretive guideline development for Division inspectors and investigators. These guidelines will support practitioner quality improvement and self-audit capacity as well as consistent enforcement by the Division. Currently a draft inspection tool is under development with consultant support and a planned stakeholder process to assure updated and uniform management of compounding pharmacy inspections and investigations. Draft guidance is expected to be completed with stakeholder review commencing in early spring of 2014. Similar work is being completed for dental offices.

Transforming IT capacity to support better enforcement has been a critical need for some time. A large number of outstanding MLO and other software and hardware needs within the Division have been delayed due to insufficient IT capacity. New FY2014 appropriations are anticipated to address a number of these pending requests; strategies to facilitate more timely IT enhancements were discussed with EOHHS last August and September.

MLO upgrades are underway to better capture activities throughout the enforcement process from complaint assignment to resolution. Among other things, a draft Probation Monitoring Policy & Procedure that will allow probation compliance to be monitored through MLO has been developed and will be finalized in the spring. Additional MLO related procedural and data collection changes include revised enforcement complaint activities panels and new tracking capacity

for cases that are pending hearing counsel. A staff survey was conducted to assess staff enrichment, support, and training needs in this and other arenas the results of which are being incorporated into a new all-staff training schedule.

III. IMPROVING QUALITY AND EFFICIENCY

- A. Quality Improvement:** Many aspects of the strategic planning process have quality improvement embedded within their objectives, including understanding and implementing a Just Culture approach; creating systematic case-based stratification, assignment and processing; and assuring the improved competencies and consistent practices among Division investigators and enforcement staff. In addition, strategic planning for quality improvement focused on determining Board and staff-based capacity development needs with a particular focus on developing a comprehensive approach to training for staff and Board members, and building a Division-wide quality assessment and improvement plan.
- **Board and staff capacity development:** HPL leadership identified a more comprehensive approach to Board and staff capacity development, training and support as critical to promoting improved quality across licensing, inspections, and enforcement functions.
 - **Status:** A staff survey and a review of both Board member and staff training participation over the last two years has been completed and key areas of training have been identified as essential to increased efficiency, quality and performance.

Currently, training available to all staff has primarily focused on human resources requirements and writing, communication, presentation development, and project management skill development. While many investigators had taken the basic CLEAR training provided by the national Council on Licensure Enforcement and Regulations, going forward, all existing and new investigators will be required to do so. This training addresses regulatory board processes and investigational techniques. As part of training-related quality improvement strategies forthcoming from this report, Advanced CLEAR training will be made available for prosecutors, investigators, complaint resolution coordinators and board counsels, as resources allow.

All Boards have selective discipline-specific and other training requirements. For example, Dental Board investigators are trained in Risk Management, Evidence Based Research, Nitrous Oxide-Oxygen Management, and Sedation Techniques, among others. The Nursing Board has had staff development opportunities over time; in the last year, for example, Nursing Board staff participated in programs and various trainings addressing nursing licensure qualification and practice standards, complaint investigation methods and legal consideration, advanced nursing practice scopes of practice and regulatory board monitoring programs.

The Division also has the capability to respond to urgent training needs as seen most recently in HPL's response to the compounding pharmacy challenges. There was extensive training of investigators in national best practices in sterile compounding pharmacy management which included training regarding FDA cGMP and USP797 standards. Pharmacy Board staff has also participated in FDA training

related to Manufacturing Principles for Processing Sterile Medical Products, and completed Critical Point's Sterile Compounding Boot Camp. To meet the critical investigational and case support needs, legal and other staff from elsewhere in HPL were cross-trained to support pharmacy complaint management. Additional and continued training in 797, sterile compounding, 795 training, risk management, and continuous quality assurance is planned.

The staff survey revealed additional areas of content expertise development desired by investigators, attorneys, and management staff as well as broad staff interest in improved understanding of administrative and other internal systems management. The Division intends to move toward a more uniform strategy of skill and competency development across the Boards as well as continuing to assure discipline specific training. As an example of planned shared content expertise development, Dental Investigators participated in the National Association of Drug Diversion Investigators in September 2013.

Senior staff is currently preparing Board-specific training requests. A preliminary comprehensive training plan has been drafted and is currently under review by senior management and the respective Boards.

- **HPL Quality Assessment and Improvement Plan:** The Division plans to institute standardized approaches to quality assessment and improvement across the Boards, recognizing that there are differential requirements in the various disciplines and in the volume of practitioners and facilities – as well as resources – that shape the obligations and opportunities of each unit. Assuring an effective feedback loop to licensees is a critical aspect of achieving overall quality improvement and shared vigilance.
 - **Status:** The alignment of complaint management processing underway through the newly established acuity management plan, and newly developed policies relating to specific risk management and discipline concerns will provide a platform for regular case disposition reporting and for ongoing assessment of the extent to which similarly situated complaints are being handled consistently across the Boards. The formative review of the acuity based case management system provides a snapshot for differential complaint management that will be one focus of quality improvement. A new Compliance Officer is responsible for assisting in the development of internal dashboards and comprehensive statistical and other analyses, conducting peer and other literature reviews, and developing presentations and reports to support ongoing HPL workforce quality improvement training and analysis among senior management and investigational and other staff.

Functional staff audits revealed the important role of the Practice Coordinator in the Board of Nursing both in terms of creating an ongoing dialogue with the field and in functioning as an important feedback loop for the nursing profession. While there had previously been staff delegated partially to perform a similar function within Pharmacy, going forward the Division has established a Quality Assurance Pharmacist in the Board of Registration in Pharmacy to focus solely on Quality Assurance issues. In addition, positions for a Pharmacy Compliance Officer and a Director of Pharmacy Compliance have been established and were filled in early 2014. All three of these new positions create expanded capacity to build clinical and

other performance competencies in the field and to effectively communicate critical investigation and literature-based findings to support rapid improvement cycles.

An overall quality improvement plan for the Division was completed in December 2013 and draws on findings from a multi-state review of health professions board annual reports and reviews of HPL case processing. This improvement plan will forecast an assessment of the first year of implementing the new policies and procedures adopted or recommended in this report. As part of the overall plan, expanded web-based investigational and other performance, risk management & quality improvement information access addressed elsewhere in this report will provide an important mechanism for sharing real-time case data and alerts with the field.

Finally, investigational IT support, discussed in the next section, will add to quality improvement efforts in field inspections as well as improving efficiencies in Division workflow.

B. Strategies to Improve Efficiencies focused on aligning and restructuring workflow processes, personnel responsibilities and IT infrastructure across the Boards to the maximum extent possible to address operational consistency as well as facilitate redundancy wherever possible.

- **Aligning and restructuring workflow and personnel responsibilities**

- **Status:** Crucial to optimizing the effectiveness of Board and staff capacity is maximizing the extent to which staff authority can be used appropriately. Selected state reviews of health profession board delegation and an analysis of the HPL practices revealed opportunities for improving and expanding staff authority and streamlining and standardizing complaints and other matters going before the Boards. As a result, preliminary draft policy provisions have been drawn up to align components of the following enforcement and complaint resolution practices across Nursing, Dentistry, Pharmacy, and Multi-boards:

- Dismissal of Complaints without Prejudice; Disposition of Complaint by Consent Agreement for Discipline; Imposition of Suspension, Surrender, Revocation of License or Right to Renew Complaint; Referral to the Office of Prosecution; Termination of Probation; License Reinstatement; Reciprocal Discipline; and Renewal of Expired Licenses with Report of Out of State Discipline.

Opportunities for further workflow improvement have become apparent as a result of the preliminary evaluation of the proposed case stratification and acuity-based complaint management plan. These are expected to reduce the average length of time to case disposition for all complaints that do not go onto full prosecution. Additionally, it is anticipated that licensing workflow changes and IT upgrades, including expanded contracting of license processing functions, will result in opportunities for further staff function restructuring. The staff survey identified additional areas for staff development and efficiencies.

Other cross-Board alignment underway includes centralizing CORI management and re-structuring CEU data collection and random audit processes. Alternative processes for managing and auditing CEUs were reviewed across fifteen states, including the following four states in New England; ME, VT, RI, and NH. This review included an assessment of internally administered and outsourced systems of managing CEU compliance. Planned developments in this arena will potentially require the reassignment of existing personnel.

Among the lessons learned from the compounding pharmacy review process have been the opportunities – and crucial need – for building redundant capabilities in legal, investigational and other administrative support staff needed for critical incident management. As a result, the comprehensive training plan to be completed in 2014 will include cross-training for staff in these areas.

- **Strengthening IT Infrastructure**

- **Status:** MLO changes to support the acuity-based case stratification and management structure have already been put in place. Additional upgrades are planned to incorporate investigator case notes and improve supervisor case tracking, audit capability, report functions, other system linkages, and dashboard development. Migration of all licensing processes to a single web-based platform is planned for 2014.

Planned laptop and other mobile inspection platform development and distribution for field investigations is expected to result in more timely, secure and standardized investigation data submissions. Expanded access to cameras, portable printers, increased server capacity and other resource enhancements are anticipated to improve case documentation quality and case disposition timeliness.

Upgrades are also anticipated for the new Dental Assistant online application process, including testing, before the registration process for dental assistants can fully be implemented. A Dental Program Coordinator is being hired and will handle the Dental Assistant online Application process. Other IT capacity development is planned to assure implementation of needed data system improvements to capture licensing date, fees, training, and other indicators for this expanded arena.

IV. IMPROVING TRANSPARENCY AND CUSTOMER SERVICE

A. Strategies for Improving Transparency focused predominantly on increasing and facilitating public engagement and information dissemination regarding Board composition and decision-making, including complaint processing and case disciplinary status.

- **Public Information & Engagement:** Many recommendations from the Special Commission, as well as ongoing efforts within the Boards, have focused on making Board processes and case disposition information more easily accessible. Additionally, HPL has been committed to supporting more extensive stakeholder engagement.
- **Status:** Recent interpretive guidance from the Office of the Attorney General has resulted in re-structuring the Open Meeting Law compliance of HPL Boards.

Training on Open Meeting Law and quorum compliance for all boards and staff was conducted in November of 2013.

Public record request management is a critical part of maintaining transparency regarding Board processes. To assure consistent management, and legal compliance, all public record requests will be streamlined and go through one coordinator. New policies and procedures for managing FOIA and media requests will be finalized in the spring.

Website re-structuring is planned for 2014 and will feature expanded complaint and case disposition information and expanded HPL Board member and meeting scheduling information. The website will have the capacity for more comprehensive and timely postings regarding Board actions and relevant quality improvement and health alert information. Additionally, planned installation of the file management software program Documentum will facilitate public access to otherwise unrestricted Board documents.

A review of best practices in state health profession licensure boards identified several models of comprehensive annual reports that would provide a new mechanism for stakeholder and broader public communication for the Division. A template was developed and will form the basis for a new HPL Division annual report the first issue of which will be published in 2014 for the FY2013.

An assessment of existing HPL Board stakeholder processes is underway to assure maximum ongoing engagement with the public and with representatives of the various Division-related health care disciplines and facilities. As part of the ongoing response to the compounding pharmacy review, HPL is convening a stakeholder group to review a pending draft inspection tool for compounding pharmacy inspections, whose work will continue through the spring of 2014. Content expertise-based advisory committees to the Board consistent with recommendations from the Special Commission and recent legislation are under development and will be formed by the end of 2014. Additionally, the Division Director has had numerous meetings with various stakeholders since stepping into the role and maintains an open-door policy to encourage stakeholder engagement.

- **Board Composition, Terms, Etc.** The Special Commission's recommendations, the recent compounding pharmacy legislation, as well as emerging national best practices in health professions licensure boards address diversifying Board membership to maximize public engagement and minimize conflict of interest while maintaining adequate discipline expertise for accurate case disposition.
 - **Status:** The HPL Division is completing an all-Board and multi-state assessment of potential conflict of interest and public and discipline-related representation concerns to determine potential statutory or other needed changes; this analysis will be completed for Board review in 2014.
- C. **Strategies for Improving Customer Service** focused predominantly on reducing licensee application and renewal related burdens, improving web data and information

access, and increasing the availability of healthcare delivery quality improvement information, communication, and support.

- **Status:** Planned licensing IT platform changes are scheduled for early 2014; they will greatly relieve initial and renewal licensing. Anticipated changes to CEU management will permit easier attestation as well as auditing and will relieve the burden on other complaint investigations. Planned quality assurance and quality improvement developments will permit better communication with the field, stakeholder engagement, and technical support.

Public records request management will be centralized and have new standardized processing policies across all Boards and the Bureau.

Improved sound amplification and video systems have been installed in the Division's public hearing rooms, increasing the ease with which meeting attendees will be able to hear the discussions of HPL Boards.

V. CONCLUSION

For over six months senior HPL staff, with consultant support, have been engaged in an extensive review of the operations of the Division, as a whole, and the nine Boards that it supports. This review grew out of the Bureau-wide quality improvement efforts begun in 2011; it was given further urgency and impetus by the compounding pharmacy challenges that emerged in late 2012. The process has had a unifying approach regarding achieving improved and more efficient oversight through reliance on best practices in the field and a commitment to achieving alignment and consistency in operations across the Division wherever possible.

Inter-related priority areas of strategic opportunity evolved and include:

- Risk Mitigation & Enforcement
- Quality Improvement & Efficiency, and
- Transparency & Customer Service.

An ambitious Implementation Workplan for 2014 is already underway and provides the platform for assessing the quality improvement the Division seeks to achieve.

This work would not have been possible without the dedicated assistance of staff across the Division who participated in the staff survey, multiple data and informational requests, extensive input into performance assessments and proposed strategies, and many rounds of editing.

The commitment to improving and assuring the health and safety of the public is the motivating force for the work of this Division and will be the basis for succeeding in achieving the goals of this strategic plan.

ADDENDUM: IMPROVING COMPOUNDING PHARMACY LICENSING AND OVERSIGHT

In the wake of the fungal meningitis outbreak, the Administration undertook a comprehensive approach to improving state oversight of the compounding pharmacy industry. A series of aggressive monitoring, investigation, and enforcement activities went into place immediately, including the issuance of emergency regulations, and the Governor convened a Special Commission to provide a framework for future improvements. This section summarizes the status of the Special Commissions' recommendations as well as administrative and other developments undertaken since fall 2012.

- A. Compliance with Special Commission Recommendations:** In January 2013, the Special Commission on the Oversight of Compounding Pharmacies issued their recommendations, many of which relied upon statutory changes that are soon to be finalized. Nonetheless, the Bureau and the Division began transformation efforts consistent with many of the recommendations, summarized below.
- Best practice reviews of the following arenas were completed to support potential new regulatory, accreditation, and other requirements after legislative action:
 - Existing compounding pharmacy regulation, accreditation and reciprocity/out-of-state pharmacy licensing processes;
 - Models for single regulatory authority for pharmacy practice across freestanding, physician-office, and hospital-based pharmacists and pharmacies;
 - Pharmacy fee schedules by licensure categories, disciplinary actions, and fines;
 - Continuing education requirements for compounding pharmacists and pharmacy technicians.
 - Formation of the recommended content-specific advisory groups is being addressed by the Board of Pharmacy in 2014. These groups will develop recommendations regarding non-residence licensure for out-of-state pharmacies and options for centralizing oversight of all pharmacies.
 - Board of Pharmacy members will complete conflict of interest training in 2014.
 - Development of a comprehensive ongoing training program addressing inspections of sterile and non-sterile compounding pharmacies along with newly emerging areas in pharmacy practice as part of the overall HPL Division training strategy. As part of this effort, the following activities have already been undertaken:
 - A total of 4 have completed USP 797 training.
 - The following training opportunities are part of the preliminary training planned for 2014:
 - Investigator interview training, CLEAR training; both webinars and an in-house specialized training for investigators, continued training in 797 and 795, risk management, and continuous quality assurance.
 - Board member information, as recommended by the Commission, is currently posted on the website as well as standardized board meeting minutes and agendas for the Board of Registration in Pharmacy from 2011-2013.
 - Website development to accommodate recommended posting of summary complaint status and disposition is underway and an implementation plan will be completed in the

spring of 2014. Best practice models from other state websites were reviewed and preliminary templates have been drafted.

- Just Culture training for Board and staff is planned to take place in 2014 as part of a Bureau-wide strategy recommended by the Commission.
- Enhanced inspections of compounding pharmacies began in October 2012 and are summarized in the next section. New funding for the Division will allow a more aggressive schedule of inspections to occur. The schedule for FY2014 was finalized in September.

B. Other Compounding Pharmacy Improvement and Oversight Activities Undertaken since Fall 2012

Multiple regulatory, monitoring, enforcement, training and other administrative efforts have been undertaken since fall 2012 to aggressively address the compounding pharmacy challenges. They include:

- Promulgation of emergency regulations in November 2012 which included newly required data reporting regarding compounded products, volume and distribution data, and self-report of federal or other state investigations.
- The first wave of unannounced inspections of all sterile compounding pharmacies, with support from Comprehensive Pharmacy Services, began in fall 2012 and was completed in early January 2013. These inspections resulted in;
 - Partial or complete cease and desist notices to 11 pharmacies.
 - Deficiency correction plan requirements for 21 pharmacies.
 - Restricted or surrendered licenses for 4 pharmacies.
- Ongoing, unannounced inspections of compounding pharmacies. Frequent communication with sterile compounding pharmacies, and noticeable inspector field presence.
- Collecting, reviewing, and responding to reports of abnormal results and positive environmental sampling tests; monitoring pharmacies' corrective actions; educating pharmacy staff on appropriate responses.
- Educating pharmacists in the field on engineering controls, process validation, room design, sampling/testing, cleaning, best practices, etc.
- Developing a sterile compounding audit tool that can be used by pharmacies at any time as a self-inspection.
- More immediate response/investigation of incoming complaints regarding sterile compounding.
- Use of cease and desist authority to stop dangerous activity immediately.
- Addressing the new legislatively mandated reporting requirements which include; submitting an annual report by December 31 of each year that details investigatory and disciplinary actions conducted by board, each complaint, date of complaint, violation alleged, name of collaborating agencies, and summaries and rationale for final decision of board. This report will be available to the public, all hospitals, pharmacies, and health care providers in the state.
- Extensive review and study of proposed federal legislation, testimony, and recommendations regarding sterile compounding and State and FDA authority.
- Compounding pharmacy related investigator training for 4 individuals, including training on USP 797 by FDA and industry experts.
- Cross-training of nursing investigational and legal staff to support expanded pharmacy inspection needs.

- Completion of expanded Board delegation / staff authority policy to assure improved allocation of staff and Board resources to priority cases.
- Establishment of a New England Compounding Pharmacy Consortium that will facilitate timely inter-state information exchange.
- Many system improvements across the Division that include:
 - Re-structuring of complaint processing to assure acuity-based stratification and priority-based management of all cases.
 - Re-structuring of MLO to improve case tracking.
 - Re-structuring of standard website Board and complaint related information.
 - Review and pending revision of Good Moral Character, CORI, continuing education and disciplinary policies to maximize alignment with national best practices and assure standardized management, where appropriate, across the Division.